DRAFT: CAP VENDOR Q&A December 19, 2005
(Third installment)

Operational Issues:

Q: Will physicians be allowed to use the CAP to develop an inventory of drugs?

A: No, physician offices will not be allowed to build an inventory of CAP drugs. As discussed on page 39047 of the July 6, 2005 Interim Final Rule with Comment, the CAP utilizes a beneficiary specific ordering process and an emergency replacement procedure, and it does not contemplate the development of a stock of inventory in the physician's office. We believe that because of potential program integrity and drug diversion concerns, the emergency replacement provision is the more appropriate way of providing needed drugs to beneficiaries when the beneficiary's clinical condition does not allow time to obtain the drug from the approved CAP vendor. In the CAP final rule (70 FR 70248) we stated that in the event a participating CAP physician administers a smaller amount of the CAP drug than was originally intended, or does not administer the drug in the time frame specified on the prescription order, that the physician must contact the approved CAP vendor to discuss what to do. We stated that if it was permissible under State law, the drug was unopened, and the participating CAP physician and the approved CAP vendor agreed, the physician could retain the drug for administration to another beneficiary. However, a new prescription order and a new beneficiary specific prescription order number would need to be created before the drug could be administered. In addition, in the IFC (70 IFC 39041) we specified that participating CAP physicians may place an order for a beneficiary's entire course of treatment at one time, and with the physician's agreement, the vendor may ship the course of treatment at one time, or may choose to split shipments into smaller parts as long as the shipments arrived at least two business days prior to the administration date specified in the prescription order, consistent with routine delivery guidelines.

Q: Can physicians participate in both the CAP and ASP systems?

A: A physician can not participate in both the CAP and ASP systems for the same drugs in the same practice. As discussed on page 70257 of the November 21, 2005 final rule, if a group practice has elected to participate in the CAP, and a physician is a member of the group, he or she has reassigned his or her benefits to the group, and is billing using the group's PIN, then the physician can not "buy and bill" separately from the group outside of the CAP. However, if a physician is a member of a group practice but does not reassign his benefits to the group and bills using his or her individual PIN, rather than the group's PIN, the physician can make a determination about whether to participate in the CAP separate from that of the group. In addition, all participating CAP physicians may continue to bill under the ASP methodology for drugs not included in the CAP, or in

cases where a beneficiary requires a particular formulation of a drug that the approved CAP vendor does not supply, using the "furnish as written" process.

Q. How will payment be made for single indication orphan drugs that the approved CAP vendor requests to voluntarily add to their CAP drug list if they do not have a weight?

A. In the November 21 Final Rule with comment (70 FR 70242) we stated that payment for these drugs would be made at ASP + 6 percent. The ASP + 6 percent price that the approved CAP vendor will receive for the drug will be the price in effect for the quarter that the addition to the vendor's list takes effect. For example if the approved CAP vendor receives permission from CMS to add a single indication orphan drug to his or her CAP drug list beginning January 1, 2006, the price for the drug will be the ASP price on the January 1, 2006 ASP + 6 pricing file. Future updates to the ASP + 6 prices for the drug will be based on the process described in the July 6, 2005 interim Final Rule with comment (70 FR 39075). Updates to the payment amount will be based on the mechanism for annual updates of single price amounts based on the approved CAP vendor's reasonable net acquisition costs.

Vendor Requirements

Q: How are unused drugs associated with an NDC that contains several vials to be managed?

A: A: In the July 6 2005 Interim Final Rule with comment (70 IFC 39061) we stated that "packages containing multiple individual units of drug (like vial trays) may be split into quantities that are appropriate for a beneficiary's dose." The remaining vials would be retained by the vendor. Consistent with Medicare billing rules, only the quantity actually administered to the Medicare beneficiary may be billed to Medicare by the vendor. The vendor claim would specify the HCPCS code for the drug and the number of units of the drug that were administered to the beneficiary.

Claims Processing

Q: If the CAP physician submits a drug claim to the local carrier later than the 14 day claim filing period after drug administration, will that claim be rejected or delayed by the carrier? In this situation, what will be the impact on payment of the drug vendor's claim? If the CAP vendor submitted its drug claim to the designated carrier in a timely manner relative to the date of intended drug administration, but the CAP physician submitted a drug claim to the local carrier that was not 'clean' (wrong prescription number, or other error), how much additional time will CMS allow the CAP physician to resubmit a 'clean' claim?

A. Medicare regulations at 42 CFR 424.44 define the timely filing period for all Medicare fee-for-service claims. In general, claims must be filed on, or before, December 31 of the calendar year following the year in which the services were furnished. For example, a Medicare supplier or provider who treats a Medicare beneficiary in March 2005 would need to submit its claim to the Medicare program by December 31, 2006. However, if a supplier does not submit the claim within one year of the date of service, the Medicare payment is reduced by 10%.

For physicians who elect to participate in the CAP, we have instituted a requirement that they file their Medicare claims within 14 days of drug administration. If a participating CAP physician routinely fails to abide by this requirement and the vendor is unable to resolve the situation on its own, the vendor may ask for the assistance of the designated carrier's dispute resolution staff. The designated carrier would investigate the complaint and could decide to recommend that CMS terminate the physician's participation in the CAP.

Payment to the approved CAP vendor is dependent upon the participating CAP physician's filing of the drug administration, and the physician's claim being approved for payment by the CMS claims processing system. If the physician claim is not received by the central CMS claims processing system within 90 days of the date the approved CAP vendor's drug claim is filed, the claims processing system will deny the approved CAP vendor's claim. At any time during this process, the approved CAP vendor may contact the designated carrier for assistance in determining the status of his or her claim. The vendor is also free to contact the participating CAP physician to determine whether the claim has been filed.

If the approved CAP vendor's claim is denied because the physician's claim has not been submitted, the approved CAP vendor may request that the designated carrier reopen and reprocess his or her claim after the participating CAP physician's office staff instruct the vendor's staff that the physician's claim has been paid. If a claim is returned to the participating CAP physician because it is not processable (not clean), then the timing requirements for submitting a claim revert to the Medicare regulations at 42 CFR 424.44 (cited above) that define the timely filing period for all Medicare fee-for-service claims. If a supplier does not submit a claim within one year of the date of service payment by the Medicare program is reduced by ten percent.